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| EXAMINER |
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RYCKMAN, MELISSA K

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3734

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09/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/613,443

Applicant(s)

GOLDFARB ET AL.

Examiner

Melissa Ryckman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on received on 6/21/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,67 and 72-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,67 and 72-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims filed 6/21/07. Claims 20,67 and 72-85 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20,67,72-82, 84 and 85 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuehn et al. (US 6165183).

Regarding Claim 20, Kuehn teaches an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflet, the leaflets having a superior surface on a first side, and an inferior surface on an opposing side, the apparatus comprising: a pair of articulating arms (440) coupled together and movable from an open position in which portions of the articulating arms are spaced apart (fig. 20) to a closed configuration to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other; a control mechanism (456) operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the arms can be closed to engage the leaflets and thereafter be opened to allow release of the leaflets (it is noted that since control mechanism (456) may be pulled to draw the graspers toward superior elements to grip the leaflets, it may also be pushed away from the leaflets thereby releasing them); a central member (446) coupled to a shaft (441) (it is noted that the entire device may be disassembled), the shaft adapted for delivering the articulating arms into a heart, the central member (446) being detachable from the shaft (441) while the shaft is in the patient's body (Fig. 20), the articulating arms (440) being movably coupled to the central member (446) and implantable in the patient's body to maintain the leaflets in the coapted configuration after the shaft has been removed from the patient's body (it is noted that although articulating arms 440 are attached to a delivery catheter, they are implanted as seen in Fig. 20); and a pair of superior elements (450) movably coupled to the central member (444) (it is noted that since central member and arms 450 are both on shaft 441, they are operably coupled together), the

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superior elements being configured to engage the superior surfaces whereby the leaflets may be pinched between the articulating arms (440) and the superior elements (450), and wherein the superior elements are resiliently biased into an extended configuration in which portions of the superior elements are spaced apart from the central member (446) for engaging the superior surfaces of the leaflets (Fig. 20)

Regarding Claim 67, Kuehn teaches an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising: a flexible shaft (441) having a proximal end and a distal end; a pair of articulating arms (440) coupled together near the distal end of the flexible shaft (Fig. 20) and being movable from an open position in which portions of the articulating arms are spaced apart (fig. 20) to a closed position in which portions of the articulating arms are closer together (it is noted that when the graspers are holding the leaflets they will be drawn closer together) and to positions therebetween, the arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a copated configuration in which portions of the superior surfaces are facing each other; a control mechanism (456) operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms; and a pair of superior elements (450, 452) movably coupled, the articulating arms (440) and superior elements (450) are moved independently of one another and can be closed to engage the leaflets (Fig. 20) and thereafter be opened to allow release and recapture of the leaflets prior to implantation

of the articulating arms in the patients body to maintain the leaflets in the coapted configuration after the flexible shaft (441) has been removed (Fig. 20).

Regarding Claim 72, Kuehn teaches the apparatus of claim 20, wherein the central member (446) is configured to be positioned through the valve between the leaflets (figs. 20 and 21, when the leaflets 440 are open 446 passes through the valve 122 and 124)

Regarding Claim 73, Kuehn teaches the apparatus of claim 20, wherein the superior elements (450,452) are coupled to a conduit (444) slidably coupled (Fig. 20) to the central member (446).

Regarding Claim 74, Kuehn teaches the apparatus of claim 20, wherein the articulating arms (440) have engaging surfaces for engaging the surfaces of the leaflets (fig 20)

Regarding Claim 75, Kuehn teaches the apparatus of claim 74, wherein the engaging surfaces have teeth (see distal-most end of articulating arms (440)).

Regarding Claim 76, Kuehn teaches the apparatus of claim 20, wherein the shaft (441) is flexible and configured for positioning through a blood vessel into the heart (it is noted that since as seen in fig. 20, shaft is in the heart, it is therefore flexible and configured for positioning through a blood vessel into the heart)

Regarding Claim 77, Kuehn teaches the apparatus of claim 76, wherein the shaft, articulating arms and central member are slidably positionable through an endovascular sheath (it is noted that endovascular sheaths come in many sizes and the

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device of Kuehn since it is meant for endovascular procedures, is capable of being slidably positionable through an endovascular sheath)

Regarding Claim 78, Kuehn teaches the apparatus of claim 67, wherein the articulating arms (440) have engaging surfaces for engaging the surfaces of the leaflets (fig 20).

Regarding Claim 79, Kuehn teaches the apparatus of claim 78, wherein the articulating arms engage the surfaces of the leaflets without penetration thereof (it is noted that the teeth as seen on articulating arms 440 have blunt tips)

Regarding Claim 80, Kuehn teaches the apparatus of claim 78, wherein the engaging surfaces have teeth (see distal-most end of articulating arms (440).

Regarding Claim 81, Kuehn teaches the apparatus of claim 67, wherein the shaft, articulating arms and central member are slidably positionable through an endovascular sheath (it is noted that endovascular sheaths come in many sizes and the device of Kuehn since it is meant for endovascular procedures, is capable of being slidably positionable through an endovascular sheath).

Regarding Claim 82, Kuehn teaches the apparatus of claim 67, wherein the shaft (441) is flexible and configured for positioning through a blood vessel into the heart (it is noted that since as seen in fig. 20, shaft is in the heart, it is therefore flexible and configured for positioning through a blood vessel into the heart).

Regarding Claim 84, Kuehn teaches an apparatus of claim 67, wherein the control mechanism (456) is adapted to open and close the articulating arms in tandem.

Regarding Claim 85, Kuehn teaches an apparatus of claim 67, wherein the superior elements are resiliently biased (it is noted that all materials have some sort of resiliency associated with them).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn in view of Oz et al. (US 6269819). Kuehn teaches all limitations of preceding independent claim 67, but fails to teach wherein the control mechanism is adapted to open and close each articulating arm independently. Oz teaches a device for use on the heart leaflets comprising a control mechanism adapted to allow each articulating arm to move independently in order to provide precise control over the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

the device of Kuehn with a control mechanism adapted to allow each articulating arm to move independently in order to provide precise control over the device.

Response to Arguments

Applicant's arguments filed 6/21/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Kuehn fails to teach or suggest that graspers are articulated
- The graspers of Kuehn are withdrawn, and they can not remain in the patients body.
- The articulating arms of Kuehn are not coupled with the central member
- The combination of Kuehn and Oz fail to disclose every element of claim 83.

The examiner respectfully disagrees with the applicant, the graspers of Kuehn, 440, are articulated as they are distinct from each other. The graspers of Kuehn are capable of staying in the body. The articulating arms are movable coupled to the central member, as the central member helps with the placement/activation of the arms. Kuehn teaches every element of claim 67, and Oz teaches claim 83, Oz does not need to teach the grasper remains in the body.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR


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SUPERVISORY PATENT EXAMINER